DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005P–0023]

Determination That TEQUIN (Gatifloxacin) Injection, 10 Milligrams per Milliliter (200 Milligrams), Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that TEQUIN (gatifloxacin) injection, 10 milligrams (mg) per milliliter (mL) (200 mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for gatifloxacin injection, 10 mg/mL (200 mg).

FOR FURTHER INFORMATION CONTACT: Elaine Tseng, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Public Law 98–417), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive

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the prescription drug product list to the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Apotex Corp., submitted a citizen petition dated January 13, 2005 (Docket No. 2005P–0023/CP1), under 21 CFR 10.30, requesting that the agency determine whether TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing agency records, FDA has determined that TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), approved under NDA 21–062, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), was withdrawn from sale as a result of safety or effectiveness concerns. FDA's independent evaluation of relevant literature and data has not uncovered anything that would indicate that this product was withdrawn for reasons of safety or effectiveness. Accordingly, the agency will continue to list TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), in the "Discontinued Drug Product List" section of the

clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), is the subject of approved NDA 21–062 held by Bristol-Myers Squibb. TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), is an antibiotic used to treat adults with lung, sinus, or urinary tract infections.

FDA approved the NDA for TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg) and 10 mg/mL (400 mg), on December 17, 1999. On January 27, 2003, FDA received revised product labeling relating to several approved supplements for TEQUIN (gatifloxacin). This revised labeling deleted references to TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), indicating that this product was no longer being marketed. Therefore, it was moved from

Orange Book. ANDAs that refer to TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), may be approved by the agency.

Dated: 1/27/06
January 27, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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